



**Decide with Confidence**

# FDA SPL ER/DL Meeting

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# Topics



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- D&B's role on the FDA SPL electronic registration and drug listing process
- Background on D&B
- D&B Recommendations
- SPL Industry Challenges
- Discussion

## Providing Regulatory Submissions in Electronic Format – Drug Establishment Registration and Drug Listing<sup>1</sup>

FINAL GUIDANCE, May 2009

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Section A (2) What information is submitted for drug establishment registration?

*FDA intends to use the Data Universal Numbering System (D-U-N-S<sup>®</sup>) as the registration number for the electronic system. Therefore, to facilitate and expedite processing of the SPL file, the registrant should submit their D-U-N-S<sup>®</sup> Number with the registration information.*

<sup>1</sup> See <http://www.fda.gov/OHRMS/DOCKETS/98fr/2005-N-0464-gdl.pdf> for additional information

# The D-U-N-S® number provides both a widely adopted standard and unique set of capabilities



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## Data-Universal-Numbering-System

A unique nine-digit global business identification system that identifies, validates and relates more than 200 million businesses worldwide

The value D&B brings is not just its number—it is in the system we have developed for maintaining accurate, comprehensive, and timely entity information.

This system, consisting of data acquisition, standardization, matching, distribution, and quality assurance is **the** critical component in business identification.

*The number is the easy part...the system is the challenge.*

# D&B's Role in Supporting eList



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- Use of the DUNS Number provides FDA with:
  - A **universal identifier** for business entities, recognized worldwide; each site of operation has its own unique DUNS Number
  - **Continual updating and maintenance** of site level establishment information by a third party (D&B)
  - **Validation** of business information submitted to FDA
    - D-U-N-S<sup>®</sup> Number verification
    - Name and Address verification

# D&B overview



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- **D&B is a global organization**
  - Business information coverage in over 190 countries; 200+ million records
  - Offices in 37 countries
  - 5,200 employees
- **170 years** of experience - collecting, cleansing, and enriching data
- **DUNSRight™ data quality process**
- **\$260M invested each year** on data quality, collection, and maintenance
- **40 years experience** maintaining the D-U-N-S Number
- **Thousands of global data sources**
- **D&B helps our clients “Decide with Confidence”**
  - Over 237,000 customer worldwide
  - All federal government departments and most agencies
  - Over 90% of the Business Week Global 1000
- **Federal government solutions**
  - Entity Management
  - Compliance
  - Supply management
  - Federal financial assistance programs
  - Homeland security
  - Law enforcement

A vast network of company-owned and affiliated information providers help us get the global and local information you need



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# Only D&B has the five essential elements that transform information into quality insight



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# The D&B Global Database is the largest, single source of decision-ready insight



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## 20,000 Global Data Sources

Trade Data (7K sources)

Banking Information

Court & Legal Filings

Business Internet Data

Business Registries

Newspapers & Publications

Telephone Interviews

Company Financials

D&B Customer Experiences

## Database



## Information

- 200M+ business records
- 190+ countries and territories
- 1.5M daily refreshes
- 1B annual trade updates
- 100% US bankruptcy coverage

# D&B Recommendation to the SPL Community



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1. Stay proactively engaged with D&B on a regularly basis to:
  - Ensure that your business profile data is up-to-date and accurate
2. Engage with D&B well before any registration filing deadlines to allow sufficient time to address any D&B synchronizations issues.
3. D&B recommends two options\* for interacting with D&B:
  - Free service
  - D-U-N-S® Request service

*\* Refer to slide 11 for details*



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# Obtaining a D-U-N-S® Number

## 1. Free Service:

- [http://www.dnb.gov/federal\\_compliance/fda/DUNSrequest/requestGuide.html](http://www.dnb.gov/federal_compliance/fda/DUNSrequest/requestGuide.html)
- Available to support requests for D-U-N-S® Numbers for your establishments; D-U-N-S® Numbers request for your U.S. agents, importers, suppliers is not available through the no-fee service
- U.S. entity requests take up to 30 business days to complete / non-U.S. entity requests take up to 40 business days
- Users of these option should state that the request is for a free DUNS Number is for compliance with the U.S. Federal Government

## 2. Expedited D-U-N-S® Request Service: **Recommended**

- <http://www.dnb.com/dunsrequest>
- \$14.95 for each D-U-N-S® Number requested
- Requests can be made for D-U-N-S® Numbers on your establishments, as well as your U.S. agents, importers, and suppliers
- U.S. entity requests take up to 10 business days to complete / non-U.S. entity requests 20 business days
- Can be used to obtain, modify or request the creation of a DUNS Number
- Dedicated fulfillment staff for tracking requests

# SPL Industry Questions / Topics



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- Frequency of D&B database updates
- D&B response times
- Global points of contacts
- Database searching

# Open Discussion



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